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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,158	08/01/2005	Stanley George Bonney	P33086	5397

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GlaxoSmithKline
GLOBAL PATENTS -US, UW2220
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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
10/14/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/519,158	BONNEY ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15-19,21-32,34,35,37-39 and 41-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15-19,21-32,34,35,37-39 and 41-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/9/10*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 12/22/09.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 2/9/10 was filed after the mailing date of the Amendment on 12/22/09. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 15, 16, 18, 19 and 29 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Clarke et al (USPN 7,163,693 hereafter '693).

The '693 patent teaches a multi-compartment capsule dosage form comprising a body and wall extending from said body forming a series of cavities (abstract, Figure 6A, part 610). These three cavities are covered with film coatings (part 62 and 64) that are a considerably thinner than the body portion from 100-500 microns (8, lin. 15-25). These film components fit over the cavities onto the bodies at ledges at the end of the body (Figure 6C). The cavity formed on the top of body part 63 fit into the cavity space 610 in a plug and socket relationship (Figure 6A). Further the film is held in place with a weld such as an ultrasonic weld (col. 9, lin. 50-57). These disclosures render the claims anticipated.

Claims 1, 2, 5, 6, 8-10, 42, 43, 50 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Beall (USPN 4,324,338 hereafter '338).

The '338 patent teaches a multi-compartment pharmaceutical dosage form that can release it's connect within the gastrointestinal environment (abstract). The dosage form comprises a body having a base wall and a first skirt wall axially extending in a first direction ((Figure 2, part 20). The wall terminates at a rim (part 28) and further comprises a covering/film/coating that closes the rim forming a covered mouth (Figure 5, part 44). A second mouth is also formed by a second skirt wall that extends away from the first wall with a wall separating the first and second mouth (Figure 1 and 5, parts 22, and 26). The second mouth is also covered with a film covering closing the mouth (part 42 and 46). The dosage form opens and the encased substance is swallowed and released in the gastrointestinal environment. These disclosures render the claim anticipated.

Claims 1-4, 6, 7, 11-13, 15-17, 21-26, 28, 30-32, 34, 35, 37-39, 41, 44 and 50-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al (USPN 5,391,381 hereafter '381).

The '381 patent teaches a multi-component pharmaceutical from comprising a body having a base wall and skirt wall forming a first and second mouth opening that are closed by a film layer (Figures 8-10). In one embodiment the film is thinner than the base and skirt wall and is disposed within opening of the cavity and extended the length of the opening effectively closing it (Figure 7, part 124). In another embodiment the film layer is disposed between the mouth in a convex shape (Figures 11-12; parts 212 relative to cavity formed by part 202). In one embodiment the first and second mouth opening interlock and are held together with an ultrasonic weld (col. 15, lin. 40-50; Figure 11). They can in some embodiments fit together in a plug and socket relationship ((Figures 9-13 and 15). The dosage form is made by injection molding granules into the base and skirt wall, followed by filling the cavity with a drug dosage form and closing the cavity with a film (col. 18, lin. 15-60). The film comprises immediate release polymers such as hydroxypropylmethylcellulose (col. 11, lin. 50-55). The film also comprise delayed release polymers such as ethylcellulose and cellulose phthalates (col. 11, lin. 45-50). These disclosures render the claim anticipated.

Response to Arguments

Applicant's arguments with respect to claims 1-13, 15-19, 21-32, 34, 35, 37-39, 41-52 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. The newly amended claims recite that the cavities terminate in a rim where the film attaches at a ledge. This structural difference required new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618